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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,423	09/27/2001	Amos Nussinovitch	919 1002	7772

21831 7590 10/21/2003

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856422

Applicant(s)

Hessner et al

Examiner

Ladd

Group Art Unit

1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 8/4/03
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-20 is/are pending in the application.
- Of the above claim(s) 12 + 15-20 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-11, 13 + 14 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

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The amendment of 8/4/03 amended claims 1, 7 and 10.

Claims 12 and 15-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely
5 traversed the restriction (election) requirement in Paper No. 9 of 1/27/03.

Claims 1-11, 13 and 14 are examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10 ***Claim Rejections - 35 USC § 103***

Claims 1-6, 8-11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nussinovitch et al (6,068,867) in view of Soon-Shiong et al (5,762,959) and Dorian et al (5,693,514).

15 The claims are drawn to coating a cell by placing the cell in a hydrocolloid solution, removing the cell from the solution, placing the cell in a cross-linking solution to provide the cell with a thin coat of the hydrocolloid, and storing the cell in solution.

Nussinovitch et al disclose coating various materials such as bulbs, fungi, etc. (Col 3, lines 1-4) by placing material in a
20 hydrocolloid solution such as an alginate solution, allowing excess solution to drip from the material and immersing the material in a gel inducing agent such as chloride salt or calcium salt. For example, see col 1, line 42 to col 3, line 20, and Examples 1 and 2.

25 Soon-Shiong et al disclose microencapsulation of cells in alginate and Dorian et al disclose using non-fibrogenic high mannuronate alginate to coat transplants such as pancreatic islets.

It would have been obvious to apply the alginate coating procedure of Nussinovitch et al to a cell in view of Soon-Shiong et al microencapsulating cells in alginate and Dorian et al coating islets with high mannuronate alginate, and since Nussinovitch et al disclose using the coating procedure to coat different materials including fungi. Storing the cell in solution would have been obvious since Soon-Shiong et al and Dorian et al may store cells in solution. No unexpected result has been established by storing in solution as compared to drying.

10 ***Claim Rejections - 35 USC § 103***

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-6, 8-11, 13 and 14 above, and further in view of Jorgensen et al (5,293,838).

15 The claim requires the cell to be a Xenopus laevis egg or embryos.

Jorgensen et al disclose protecting an egg by encapsulating the egg in a gel material (col 1, lines 54-60).

20 When applying the coating procedure of Nussinovitch et al to a cell as set forth above, it would have been obvious to applying the coating to a Xenopus laevis egg or embryos to obtain the protective function of the coating as suggested by Jorgensen et al.

Response to Arguments

25 Applicants urge that the claims now require storing the cell in solution, and that Nussinovitch et al must dry. However, the rejection is based on applying a coating as disclosed by Nussinovitch et al to a cell disclosed by Soon-Shiong et al and Dorian et al since Nussinovitch

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et al disclose coating fungi. When coating a cell as set forth, drying would not be necessary since it is not essential for Soon-Shiong et al and Dorian et al to dry. It is well known to store cells in solution, and no unexpected result is seen from storing in solution.

5 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date
10 of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,
15 however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 703-308-0520. The examiner can normally be
20 reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



David M. Naff
Primary Examiner
Art Unit 1651

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DMN

10/20/03